

**REMARKS**

This amendment is in response to the Office Action rejection mailed on May 15, 2007.

Claims 1-61 are pending in the application. Claims 47-61 are withdrawn, claims 42-45 were allowed, claims 1, 3, 5, 7, 11, 20-25, 27, 29, 31, 32, 37, 38, and 46 were rejected, and claims 2, 6, 8-10, 12-19, 26, 28, 30, 33-36, and 39-41 were objected to.

Claims 1, 11, 20, 25, 27, 29, and 31 were rejected under 35 U.S.C. 102(a) as being anticipated by FR 2,817,463 (hereinafter Conchy). The Office Action rejection was based on an unnumbered figure from Conchy as reproduced on page 5. A translation of the document was not provided. As illustrated in the figure from the Office Action, Conchy teaches an adjustable medical device that is implanted between vertebral members comprising at least a first ring member having a first side, and a second ring member having a second side. Each member's side has successively angled ramps with top and bottom points fitted to engage with each other in an overlapping manner. The device is formed by concentrically stacking the ring members about a longitudinal axis. The members are rotational to each other about the axis by mutual cooperation and engagement of the ramps. The implant device can vary its longitudinal dimension by rotation to change the point at which the member's ramps are engaged and expand or contract in height as necessary. The members can be rotated through a minimum and maximum height based on the height dimensions of the top and bottom points of the ramps. Once the implant device is formed, the surgeon fills a central longitudinal cavity left by the stacked ring members with a substance that promotes bone growth.

Claim 1 has been amended to now incorporate allowable subject matter from dependent claim 2. The claim now includes sidewalls that extend outward from the first contact surface to partially extend around the third member. For at least this reason, independent claim 1 and dependent claim 11 are not anticipated by Conchy.

Claim 20 has been amended to now include that the second member is laterally displaced relative to the first member when moved from a first position to a second position. Conchy teaches a device where the movement between the first and second members is restricted to rotation about a longitudinal axis. This rotational movement causes the first and second members to be displaced from one another along the longitudinal axis, but not laterally. Indeed, as illustrated in the Office Action, lateral displacement of the members (i.e., movement to the left or right as viewed in the figure) would disrupt the structural integrity of the device because the members must stack upon each other. Therefore, Conchy does not teach or suggest that the members move laterally with respect to one another. For at least these reasons, claim 20 is not anticipated by Conchy.

Claim 25 has been amended to now include that the second member is laterally moveable relative to the first member. The lateral movement causes a change in lateral distances between the distal ends of the first and second members. Conchy discloses movement between the first and second members as restricted to rotational movement about a longitudinal axis with the members remaining in a concentric orientation. As discussed above for claim 20, Conchy does not teach lateral movement of the members with respect to one another. For at least these reasons, independent claim 25 and dependent claims 27, 29, and 31 are not anticipated by Conchy.

Claims 1, 3, 5, 7, 11, 20, and 21 were rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Patent No. 6,176,881 (hereinafter Schär). Schär teaches a device that is implanted between vertebral members that may telescope along a longitudinal axis to space the vertebral members. The device includes first and second cylindrical members concentrically aligned along a longitudinal axis. The sizes of the cylindrical members provide for telescoping movement to expand an overall height of the device. The first cylindrical member includes teeth positioned axially along the length that engage with teeth on a locking member. The shape of

the teeth on the first cylindrical member and the locking member provide for telescoping movement to expand the overall height, but prevent movement to contract the overall height.

Claim 1 has been amended to now incorporate allowable subject matter from dependent claim 2. The claim language now discloses sidewalls that extend outwards from the first contact surface and partially extend around the third member. For at least this reason, independent claim 1 and dependent claims 3, 5, 7, and 11 are not anticipated by Schär.

Claim 20 has been amended to include that the second member is laterally displaced relative to the first member. The lateral movement results in a height along a longitudinal axis to increase. Schär does not include lateral movement of the first cylindrical member relative to the second cylindrical member. Rather, Schär discloses that the cylindrical members remain concentric while the overall height increases. Because the members remain concentric and in general contact with one another as illustrated in the figure reproduced on page 7 of the Office Action, lateral movement of the members relative to one another would not be possible. There is no lateral movement between these members that causes the increase in height. Thus, Schär does not teach or suggest lateral movement of the members. For at least these reasons, independent claim 20 and dependent claim 21 are patentable over, and are not anticipated by Schär.

Claims 32, 37, 38, and 46 were rejected under 35 U.S. 103(a) as being unpatentable over Conchy in view of U.S. Patent No. 4,787,915 (hereinafter Brantigan).

Brantigan discloses rigid implants for insertion between adjacent vertebrae including tool receiving end faces to facilitate insertion between the vertebrae. Brantigan also discloses a tool assembly to facilitate insertion of the implants. The tool assembly includes an elongated stem with a handle attached to a proximal end and a threaded distal end adapted to mate with the tool receiving end face of the implant. An elongated sleeve is slidably mounted on the stem. An end of the sleeve adjacent the distal end of the stem includes keys or lugs adapted to engage

the end face of the implant. The threaded end of the stem is threaded into the end face of the implant, and the tool assembly is used to insert the implant between the vertebrae. Once properly inserted, the sleeve is advanced on the stem so that the keys engage the end face of the implant. The sleeve may then be used to firmly hold the implant in place without rotation as the stem is unthreaded from the end face.

Claim 32 has been amended to now include a first member and a second member, and a deployer operatively connected to at least one of the first and second members to give lateral movement of the first member relative to the second member. The first and second members each have an interior and exterior side, with each interior side having ramped surfaces positioned at an angle relative to the exterior sides. As discussed previously, Conchy does not disclose lateral movement of the members relative to one another.

Brantigan discloses an elongated stem or shaft and a sleeve slidably engaged over the shaft. If the shaft is considered to be the first or second member, Brantigan does not disclose that it has an interior side. Significantly, Figure 5 of Brantigan illustrates that the stem is a solid rod. If the stem does not include an interior side, then it cannot include ramped surfaces as required by claim 32. If the sleeve is considered to be the first or second member, the sleeve includes an interior and exterior side. However, the interior side is adapted to slidably engage the stem and does not include ramped surfaces as required by claim 32. Additionally, the sliding movement of the sleeve on the stem does not change the height between the exterior sides measured along a longitudinal axis as required by claim 32. Instead, the exterior sides remain a generally fixed distance apart as the sleeve slidably moves on the stem. Therefore, neither Conchy nor Bratigan, alone or in combination, disclose all of the limitations of claim 32.

In addition, Conchy and Brantigan could not be combined as suggested in the Office Action. Assuming that the stem of Bratigan could be operatively connected to the implant of Conchy, the stem provides only rotational movement. Rotational movement applied to

Conchy's implant, as discussed previously, would result in longitudinal movement of the individual members, not lateral movement as required by claim 32.

For at least these reasons, independent claim 32 is not made obvious over the combination of Conchy and Bratigan, and the rejection based on the combination is improper.

Claim 37 includes a first shaft attached to a first section of a spacer and a second shaft operatively connected to a second section of the spacer. The Office Action suggests that the stem and sleeve (first shaft and second shaft) of Bratigan could be attached to two separate members disclosed by Conchy. As illustrated on page 5, the Office Action proposes that the stem and sleeve could engage members M1 and M2 at openings O. Because the stem and sleeve are concentric, it would be impossible for the stem and sleeve to simultaneously engage M1 and M2. Even if the stem could extend through M1, it could only extend to the opposite side of M1. The sleeve would merely engage the outer surface of M1 around the periphery of opening O. Thus, the combination proposed by the Office Action is improper.

For at least these reasons, independent claim 37 and dependent claim 38 are not made obvious by Conchy and Bratigan.

Claim 46 includes a delivery device with a first end pivotably connected to a deploying member. Assuming that the stem and/or sleeve of Bratigan is the delivery device, there is no pivotable connection disclosed. Likewise, Conchy does not disclose a pivotable connection.

For at least this reason, independent claim 46 is not made obvious by Conchy and Bratigan.

The specification is objected to under MPEP § 608.10(o) as failing to provide proper antecedent basis for the subject matter claimed in claim 4. Claim 4 requires the first contact surface and the second exterior contact surface form an acute angle in the second orientation. Line 1 on page 6 of the Specification discloses the device can be "angled in one or more of the closed, open, or deploying orientations to conform to the dimensions of the vertebral member".

The Specification subsequently describes the movement in line 14 of page 8 wherein the "first member 20 continues to move outward from the centerline increasing the overall height of the spacer 10." Claim 4 describes the spacer in an opened orientation as in Figures 3 and 9. The first contact surface and the second exterior contact surfaces form an acute angle relative to one another in an opened orientation when the angled surfaces of the third member laterally displace the angled surfaces of the first member. This causes the first member to be laterally offset from its starting position, and its contact surface will now be at an acute angle relative to the second member's exterior contact surface. Therefore, no amendment to the Specification is required.

Claims 41, 42, and 46 were objected to because of informalities. Appropriate correction has been made to each of the claims.

Claim 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 20 has been amended and the first element reads "a first member having a first exterior contact side..." The amended claim now provides sufficient antecedent basis for "the first exterior contact side," and is now in condition for allowance.

The Office Action states that the declaration is defective because it did not "state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56." The submitted declaration includes the statement: "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. 1.56(a)."

The required content of the oath or declaration are set forth in 37 C.F.R. 1.63. This section requires that the oath or declaration "state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56." 37 C.F.R. 1.63(b)(3). Section 1.56 consists

of paragraphs (a) through (e). Paragraph 1.56(a) imposes a duty of candor upon each individual associated with the filing and prosecution of a patent application. This duty includes a duty to disclose all information known by the individual to be material to patentability.

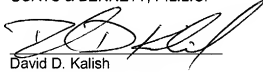
Paragraph 1.56(b) defines what is material to patentability, and paragraph 1.56(c) defines who falls within the scope of the duty. Paragraph 1.56(d) specifies how individuals other than the attorney, agent or inventor may comply with this section. Further clarification of the duty under this section for continuation-in-part applications is contained in paragraph 1.63(e). In short, the duty to disclose is set forth in paragraph 1.56(a).

Applicants' oath acknowledges the duty to disclose information which is material to the patentability of the application in accordance with 37 C.F.R. 1.56(a). Paragraph 1.56(a) states that "each individual associated with the filing and prosecution of a patent application has...a duty to disclose to the Office all information known to that individual to be material to patentability **as defined in this section.**" (emphasis added). Therefore, paragraph 1.56(a) expressly incorporates the definitions contained in paragraphs 1.56(b) and (c). Because paragraphs 1.56(d) and (e) serve to further clarify paragraphs 1.56(a) – (c), they are logically included in the statement "as defined in this section." A hypertechnical reading of paragraph 1.63 may draw a distinction between citing paragraph 1.56 versus 1.56(a) in an oath. There is, however, no legal difference between affirming compliance with paragraph 1.56(a) versus complying with section 1.56. The submitted oath affirms Applicants' compliance with section 1.56.

In view of the above amendments and remarks, the Applicants' submit that the present application is in condition for allowance and such action is respectfully requested. If any issues remain unresolved, the Applicant's attorney requests a telephone interview to expedite allowance and issuance.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'D. Kalish', is written over a horizontal line.

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